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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 2

Application Number: 09/715,965
Filing Date: November 17, 2000
Appellant(s): DENHOLM ET AL.

Patrea Pabst
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/26/2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the invention involves the use of the enzyme, method of administration and the disorder to be treated all in the same claims. The claims do not stand or fall together but for different reasons than stated by appellant. They do not stand or fall together because different claims are rejected for different reasons, such as different pieces of prior art and enablement.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,696,816	Brown	9-1987
5, 567, 417	Sasisekharan	10-1996

Takeuchi, British Journal of Cancer, 1972, 26(2), 115-119.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

It should be noted that appellant elected chondroitinase AC as the enzyme and cancer as the disorder and that the reference, WO 96/01648 (Ibex) as been dropped.

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support for the term, "an established disorder requiring angiogenesis". Nowhere in the specification can such support be found.

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Claims 1-11 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing tumor cell growth using a chondroitinase, does not reasonably provide enablement for treating an established disorder requiring angiogenesis with the enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for reducing tumor cell growth using a chondroitinase, but is not enabled for treating an established disorder requiring angiogenesis with the enzyme.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test if an established disorder requiring angiogenesis can be treated with the enzyme (chondroitinase).

Applicant has only shown in their examples that the enzyme can be used to reduce tumor cell growth. With only knowing this, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only taught how to reduce tumor growth then to expect one of ordinary skill in the art to have understood that this would work with any and all disorders requiring angiogenesis is simply not valid on its face. Disorders such as arthritis and atherosclerosis, obesity in and of themselves are unrelated and one would not make the connection of them to the enzyme with only knowing that tumors could be reduced with the enzyme since different disorders are effected differently with different treatments. Simply because the enzyme

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worked on decreasing angiogenesis with tumors does not lead one of ordinary skill in the art to believe that it would also work with arthritis, for example.

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what applicant is referring to when they state, "these enzymes expressed from recombinant nucleotide sequences in bacteria". What "recombinant nucleotide sequences in bacteria" is applicant referring to ? This is not clear on the record. Applicant has only described how to isolate them non-recombinantly. The specification does not make this term clear. Without knowing what sequences applicant is referring to, it is simply unclear what the term means.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 5, 9, 10, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi.

Takeuchi teaches that mice injected subcutaneously with solid Ehrlich ascites tumors are also injected subcutaneously with chondroitinase AC, see abstract, page 115-116, under "Materials and Methods", page 118, left column, first full paragraph, and the "Discussion". Takeuchi also teaches that the growth of the tumor cells was decreased when the chondroitinase AC was administered. The fact that the mice are

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injected with Ehrlich ascites tumor cells gives them cancer and then they are treated with the chondroitinase AC. Ehrlich ascites tumor cells are known cancer cells as is evidenced by JP 51075042, relying on abstract only.

Claims 1, 2, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown, see col. 4, lines 40-47.

Brown teaches treating the tumor of an individual with chondroitinase AC, of record. Since Brown teaches treating tumors this would include individuals with cancer and thus decreasing angiogenesis. When the enzyme is applied to the tumor it will inherently perform the claimed process.

Claim Rejections - 35 USC § 103

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasisekharan et al. (abstract, col. 1-2, col. 17, claims) taken with Takeuchi or Brown.

Sasisekharan teaches a method for inhibiting angiogenesis using heparanases. It also teaches that heparinases can be used with an infusion pump to deliver chemotherapy to tumors as well as the other methods of administration. Solid tumors are also taught to be treated.

Sasisekharan does not teach using a chondroitinase.

As is taught in both Brown and Takeuchi it is known to treat tumors and cancerous tumors with chondroitinase. Since both of the references clearly show beneficial results, then it would have been obvious to one of ordinary skill in the art to use a chondroitinase instead of a heparinase for decreasing angiogenesis.

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeuchi or Brown.

Takeuchi teaches that mice injected subcutaneously with solid Ehrlich ascites tumors are also injected subcutaneously with chondroitinase AC, see abstract, page 115-116, under "Materials and Methods", page 118, left column, first full paragraph, and the "Discussion". Takeuchi also teaches that the growth of the tumor cells was decreased when the chondroitinase AC was administered. The fact that the mice are injected with Ehrlich ascites tumor cells gives them cancer and then they are treated with the chondroitinase AC. Ehrlich ascites tumor cells are known cancer cells as is evidenced by JP 51075042, see abstract.

Brown teaches that chondroitinase AC can be injected into humans for the treatment of intervertebral disc displacement. The references also teaches that the enzyme can also be used to treat tumors, see col. 4, lines 9-53.

Takeuchi and Brown do not teach specific amounts of the enzyme to be used.

To administer the enzymes at different concentrations is simply the choice of the artisan in an effort to optimize the desired results. There is no criticality shown using such amounts.

(11) Response to Argument

Appellant has argued that the written description and enablement rejections are without merit because they have provided examples in the specification.

Appellant has only shown via their examples that the chondroitinase can be used to reduce cell tumor growth. With only knowing this, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only taught how to reduce tumor growth then to expect one of ordinary skill in the art to have understood that this would work with any and all disorders requiring angiogenesis is simply not valid on its face. Disorders such as arthritis and atherosclerosis, obesity in and of themselves are unrelated and one would not make the connection of them to the enzyme with only knowing that tumors could be reduced with the enzyme since different disorders are effected differently with different treatments. Simply because the enzyme worked on decreasing angiogenesis with tumors does not lead one of ordinary skill in the art to believe that it would also work with arthritis, for example. Thus, only knowing that one can decrease cell tumor growth one of ordinary skill in the art would not have known that angiogenesis (which covers such a broad range of diseases) would have been effectively decreased. Tumors which would cover cancer would not cover arthritis as mentioned about. How could one of ordinary skill in the art know that simply because he or she could use the chondroitinases to decrease tumor growth such as in cancer

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know that arthritis could also be decreased. There is no evidence of this in appellant's specification.

Appellants do not argue the 35 USC 112, second paragraph rejection and thus it is maintained for the reasons of record.

Appellant next argues that Brown only mentions treatment of tumors in passing and that Brown does not teach treating tumors with the chondroitinase. Appellant refers to the portion of Brown on col. 4, lines 42-45 and states that "other unwanted cartilage tissue" makes the statement of tumors invalid. This is simply not the case. For example, when Brown recites "arthroscopy of joints", Brown is clearly not referring to tumors. This is where Brown is referring to the "other unwanted cartilage tissue". Brown has made it clear that the chondroitinases can be used to treat tumors.

Next Appellant argues that Takeuchi administers the enzyme prior to or at the time of injecting the mice. There is nothing in the claims to state when the enzyme is administered. Appellant also argues that Takeuchi does not inhibit angiogenesis nor tumor growth but it says in the abstract of Takeuchi that chondroitinase Abc significantly inhibited tumor growth. Takeuchi goes on to show that chondroitinase AC also does this. Appellant argues that the mice were not patients that needed the treatment because they did not have cancer, but by injecting them with the tumors then they had the cancerous tumors. So the fact that appellant argues that the tumors were not

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established is not on point. The tumors would have been established when the mice were injected with them.

Appellant argues that Sasisehkaran teaches one about heparinases but not chondroitinases. This is why Sasisehkaran was used in a 35 USC 103 rejection. As shown in Brown and Takeuchi these references established that chondroitinases are known to be used to treat tumors with chondroitinases and that such treatments were beneficial. Thus, there was motivation to use the chondroitinases in the method of Sasisehkaran.

Appellant next argues that there is no motivation to combine Takeuchi and Brown, but these references were used in the alternative. As stated above, the ordinary artisan would have been motivated to use the proper amounts of such chondroitinases to treat the tumors since through routine experimentation one of ordinary skill in the art could have determined the proper and effective amounts to use. In fact, Takeuchi does use effective amounts and to use those as claimed by appellant would have only required further experimentation.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,



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Art Unit 1654


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May 12, 2004

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